REMARKS

Claims 33, 34, and 46-49 are pending in the application and are at issue.

The courteous interview granted to applicants' undersigned attorney and Andrei Gudkov by Examiner Cook on March 9, 2004 is hereby noted with appreciation. At the interview, the invention, the claims, and the Office Action were discussed in detail.

At the interview, the examiner requested a terminal disclaimer over applicants' issued parent application, i.e., U.S. Patent No. 6,593,353, and over applicants' copending application Serial No. 09/947,757. In response, applicants submit a timely filed terminal disclaimer over copending application Serial No. 09/947,757 concurrently with this amendment. It is submitted that a terminal disclaimer over U.S. Patent No. 6,593,353 is not proper because the present application is a divisional of the parent application. The Patent Office, by issuing a restriction requirement in the parent case, already determined that the present invention is patentably distinct from the invention in the parent application. Applicants apologize for not bringing this to the examiner's attention during the interview.

As discussed at the interview, claim 33 has been amended to more particularly recite the present invention by inserting reference to "a host." Claim 34 has been amended to reinsert preparing a host for a bone marrow transplant, and claim 46 has been converted to a dependent claim. The amendments to claims 33, 34, and 46 were discussed at the interview, and agreed to by the examiner.

The examiner also agreed to reconsider the restriction requirement, and to examine claims 33, 34, and 46 that are directed to temporary p53 inhibitors that reversibly inhibit p53. This feature of the invention was thoroughly discussed at the interview. In particular, applicants' parent application is the first application to address administration of reversible p53 inhibitors, which is counterintuitive and contrary to established knowledge because persons skilled in the art are aware that inhibition of p53 can lead to serious adverse effects, such as the onset of a cancer. Not only are the applicants the first to conceive of administering reversible p53 inhibitors, applicants have found examples of reversible p53 inhibitors, as set forth in the specification and in claims 47-49.

Furthermore, the identification of a reversible p53 inhibitor does not require undue experimentation. The reversible p53 inhibitors recited in the specification were found using a simple screening test of a chemical library. This test is set forth in the specification at page 43, lines 5 through page 44, line 10, and in Figs. 1 and 2. Accordingly, persons skilled in the art can readily determine whether a compound is a reversible p53 inhibitor through a simple chemical screening procedure.

Therefore, claim 33 is directed to a method of preventing cell death, in a host, attributable to a stress-inducing event, and various stress-inducing events are specifically listed in claim 34. Applicants submit that claims 33, 34, and 46 should be examined in their present form, and that the claims particularly point out and distinctly claim the subject matter which

applicants regard as their invention. Applicants respectfully request the examiner to reconsider these claims as they presently stand. Claim 46, which is directed to a particular stress-inducing event, particularly points out and distinctly claims the subject matter which applicants regard as one aspect of the invention.

Claims 33, 34, and 46-49 stand rejected under 35 U.S.C. §101 because a Mase et al. publication discloses immunosuppressive agents that are useful in organ transplantation, and because some compounds disclosed in that publication fail to show immunosuppressive effects. It is submitted that this rejection is in error, and should be withdrawn.

In particular, the Mase et al. publication is directed *solely* to immunosuppression and to *organ* transplantation. The Mase et al. publication is silent with respect to p53 inhibitors, let alone reversible p53 inhibitors. The use of a reversible p53 inhibitor to prepare a host for a bone marrow transplant is totally unrelated to immunosuppression in organ transplantation.

It is known that a person preparing for a bone marrow transplant often is treated with a chemotherapeutic agent. This a stress-inducing event can lead to the death of normal cells via p53 activation. By administering a temporary p53 inhibitor, p53 cannot be activated and the normal, but stressed, cells will not be killed. This mode of action is not related to immunosuppression, but is an entirely different pathway.

An immunosuppressive agent is administered to reduce the occurrence of organ rejection by the host. In the present claims, a reversible p53 is administered to protect normal cells from death attributed to a stress-inducing event. This is unrelated to a host rejecting an organ. In particular, an immunosuppressive agent could be administered with a reversible p53 inhibitor in order to reduce the occurrence of organ rejection *and* to protect normal cells from a stress-induced death.

Accordingly, as discussed at the interview, the present invention is directed to the reversible inhibition of p53 to protect normal cells from death attributable to a stress-inducing event, as opposed to immunosuppression. Therefore, the Mase et al. publication is not relevant to the present application. Furthermore, applicants have affirmatively demonstrated utility in the specification. In particular, applicants have disclosed a simple screening process for identifying temporary p53 inhibitors and have demonstrated the usefulness of temporary p53 inhibitor administration.

In summary, it is submitted that generic claims 33, 34, and 46 are patentable because no art has been found with respect to using a temporary p53 inhibitor to prevent normal cell death attributable to a stress-inducing event, either generally or from the events recited in claims 34 and 46. It also is submitted that dependent claims 47-49, which recite a specific class of temporary p53 inhibitors, also are allowable. An early and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

Respectfully submitted,

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April 2, 2004